

REMARKS

Claims 1-18 are all the claims currently pending in this Application. Claims 10-18 are withdrawn. Therefore, claims 1-9 are all the claims currently under consideration.

Listing of the Claims

In the final Office Action, the Examiner notes that in the Response to Restriction Requirement of November 17, 2005, claims 10-18 included incorrect status identifiers. With this Response, Applicants include the above Listing of the Claims, including the proper status identifiers for all claims.

Claim Rejection

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Joseph (U.S. Patent 4,604,087) in view of Molteno (GB 2,101,891). Applicant respectfully traverses this rejection.

The Examiner maintains that the subject matter of claims 1-9 is rendered obvious by Joseph in view of Molteno. Specifically, the Examiner reiterates that the positioning of tube 2 in the anterior chamber through an opening in a cyclodialysis tract necessarily teaches that the tube is adapted to locate Joseph's device on the inner surface of the sclera, in a suprachoroidal space formed by cyclodialysis, as the choroid is on the inner surface of the sclera. In support of this position, the Examiner relies upon the disclosure in Joseph which states as follows: "This figure [Figure 2] also shows the free end of the tube 2 [of the device] entering the anterior chamber 15 through an opening in the cyclodialysis tract 16, the opening being formed surgically."

With respect, the Applicant submits that the Examiner appears to erroneously equate the reference by Joseph to the "opening in a cyclodialysis tract" with the cyclodialysis tract itself, thus forming the view that the device of Joseph is positioned in a suprachoroidal space. With particular reference to Figure 2, the Applicant draws the Examiner's attention to the path traveled by tube 2, commencing with its free end positioned within the anterior chamber 15, lying about one third of the distance between the iris 14 and the cornea 13 (please also refer to text at column 4, lines 6-8). Moving towards the angle between the iris and the cornea, the tube is seen to travel between the ciliary body and the sclera (scleral spur) i.e. along the cyclodialysis tract, for a distance not more than the length of the ciliary body, at which point the tube is directed to the outer surface of the eye, through an opening in the cyclodialysis tract, the opening seen in Figure 2 as an exit point from the interior aspects of the eye to the exterior of the eye.

Thus, the tubing 2 at first travels along a short distance of suprachoroidal space, abutting the ciliary body at its posterior surface and the sclera at its anterior surface. Once outside the eye, the surface of the tubing initially abutting the ciliary body now immediately abuts the outer surface of the sclera. At a short distance, the tubing is then seen to be attached to the drainage body 3, which itself now abuts the outer sclera. The drainage body 3 is wrapped around the exterior of the eye such that in sagittal or transverse cross section (Figure 2), the drainage body is also observed on the opposite side of the eye (placement of reference number 3), also abutting the exterior scleral surface.

Accordingly, Figure 2 (and Figures 4 and 5) clearly shows that a portion of tubing passes within the cyclodialysis tract along the ciliary body, but that the greater portion of Joseph's

device actually sits outside the eye, rather than within a suprachoroidal space, as suggested by the Examiner. Drainage therefore takes place on the scleral surface, rather than within a suprachoroidal space.

The Applicant submits that there are two reasons for using the cyclodialysis tract as an entry point for the tube 2 into the anterior chamber. The first is that this entry pathway conforms with a tube curvature that keeps the end of the tube away from the corneal endothelium, which if damaged will swell and become opaque. This is in fact discussed by Joseph at column 4, lines 9-21. The second reason is that this would distinguish the Joseph shunt from that of Molten for which the entry point for the tube is usually through the sclera near the junction of the sclera with the limbus. For the latter to work, the tube is cut so that not too much protrudes into the anterior chamber. The tube in the Molten shunt ends up having to “bend” into the anterior chamber and this is facilitated by the usual practice of putting a patch graft of sclera over the tube (ostensibly to stop tube erosion through the overlying conjunctiva) as the extra force applied when the scleral patch is sewn over the tube helps to kink it into place.

The Applicant further respectfully submits that numerous disclosures made by Joseph would indicate to a person skilled in the art that Joseph’s device could not in fact be positioned within a suprachoroidal space. These disclosures are discussed below.

At column 1, line 63 to column 2, line 2, Joseph states that prior art drainage devices relying on the use of a circular plate(s) as a drainage body do not provide sufficient surface area for sufficient drainage. In consequence, Joseph instead teaches the use of a tyre-like device (drainage body) that clearly fits on the outside of the sclera (Figure 2, drainage body 3).

Therefore, this tyre-like device is distinguished from plates, the latter conceded by Joseph as providing insufficient surface area for drainage.

The drainage body of Joseph is described as a “*band having a width of at least 5mm and a length which is sufficient for the band to pass around, and sutured to, the sclera of the eye in an equatorial position...*” (Column 2, line 19). At column 2, line 59, Joseph also provides that for most eyes, “*the band preferably has a width lying in the range of from 9 to 12 mm*”, and at column 5, line 21 and line 23, the width is given as being up to 15 mm or 18 mm, respectively. Notably, Joseph also teaches at column 3, line 59, that the eye (reference number 10 of Figures 2, 4 and 5) is an “*averaged-sized diseased eye, that is to say one having a diameter of about 25 mm.*” Given that in cyclodialysis, by definition, only the ciliary body is detached from the sclera, and that the ciliary body does not extend posteriorly beyond 4.5 -5.2 mm nasally and 5.6-6.3 mm temporally, it would be abundantly clear to a person skilled in the art that Joseph's device, having an average band width of from 9 to 12 mm, would simply not fit in the space created by detachment of the ciliary body. Accordingly, a person skilled in the art would conclude from reading Joseph that his device could not be locatable in the suprachoroidal space on the inner surface of the sclera.

At column 4, lines 41-46, Joseph expresses concerns of the effect of intra-ocular pressure becoming too low as a result of aqueous humor draining too quickly immediately after entering the eye. Joseph explains that this can lead to “*large choroidal detachments forming, which in turn are associated with a tendency to damage the lens of the eye.*” The Applicant submits that if this scenario were to occur, and if Joseph's shunt was suprachoroidal, the risk of choroidal

detachment would be significantly greater, since Joseph's device would be sitting in the suprachoroidal space, facilitating choroidal detachment. Indeed, Joseph teaches placement of his device on the outer scleral surface. Accordingly, the Applicant submits that a person skilled in the art would appreciate that Joseph's shunt would not be appropriate for suprachoroidal placement. Joseph's silence with respect to suprachoroidal placement is particularly relevant given his concerns about choroidal detachment.

At column 2, line 65 to column 3, line 14, Joseph describes attaching extra drainage bodies to his shunt, should the initial shunt procedure not provide sufficient drainage. Specifically, Joseph discusses extension of the tube from the first drainage body to an additional drainage body, stating that “*the additional drainage body can be implanted (preferably under the scalp) some time after the initial operation...this can be accomplished by simple extra-ocular surgery.*” The Applicant submits that in light of this passage, a person skilled in the art would well appreciate that if Joseph's device were in the suprachoroidal space, it would not be possible to connect it to an extra drainage body by an “*extraocular procedure*”, as it would be necessary to open the eye, i.e. an intraocular procedure would be required to reach an implant supposedly in the suprachoroidal space. Accordingly, a person skilled in the art would understand without difficulty that Joseph's device could not be positioned suprachoroidally, as this would exclude the possibility of attachment to the device of additional drainage bodies if required. It would be clear to a person skilled in the art that Joseph did not intend to place his device in the suprachoroidal space, and that Joseph's design for a drainage device is reflective of this.

At column 3, lines 62 – 65, Joseph teaches suturing of the shunt to the sclera. Notably, there is no description of how this would be done. The Applicant submits that were Joseph's device to be placed suprachoroidally (hypothetically speaking, as Joseph's device would not fit), suturing the device to the inner surface of the sclera would not be possible without potentially damaging the inner eye. This is because suturing in this case would involve penetration of the needle from the outer surface of the sclera, through the entire thickness of the sclera, and then blindly into an implanted suprachoroidal device. Furthermore, the suprachoroidal space would need to be stabilized as it would move as the needle were being forced into it. Thus, the Applicant submits that a person skilled in the art would not choose to place Joseph's device suprachoroidally and would understand the unsuitability of this device for suprachoroidal positioning, given that Joseph teaches suturing to secure positioning of the device.

In view of the issues presented above, the Applicant submits that the person skilled in the art would not consider Joseph's drainage device to be locatable in the suprachoroidal space. This is particularly the case when these issues are considered together, i.e. in the totality of the teaching by Joseph,

Accordingly, the Applicant reiterates that there is no contemplation by Joseph that the device may be placed anywhere other than on the outer surface of the sclera, let alone to be located on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis. Further, to construct an aqueous humor drainage device for such a location would not have been contemplated or envisaged by a person skilled in the art prior to the present invention. Accordingly, to argue that the structure of Joseph is capable of being located on the inner surface

of the sclera is essentially immaterial as it would not have been obvious to one of skill in the art to place the Joseph device in such a location.

The Applicant further provides the following comments in support of the assertions made above. Cyclodialysis has indeed previously been considered as a technique for the drainage of aqueous humor. However it had been abandoned well before the priority date of the present application due to complications, chiefly uncontrolled low pressure (hypotony) due to failure of the cyclodialysis to heal spontaneously. Therefore, Glaucoma shunts such as those of Joseph were developed because techniques such as cyclodialysis had failed. When the Joseph shunt was conceived, suprachoroidal surgery had been abandoned and accordingly the last thing that would have been considered by one of skill in the art at the priority date of the present application would be to place a device such as that of Joseph in the suprachoroidal space. Doing so, with a shunt of the size and composition of the Joseph shunt would have resulted in significant trauma to the eye.

There have also been previous attempts at suprachoroidal shunts (see the attached documents; Rosenberg and Krupin, "Implants in Glaucoma Surgery", in *The Glaucomas* (1996), Chapter 88, pages 1783-1807; and Lee et al (1992)) however these had a high complication rate. The GlauRx trabeculo-suprachoroidal implant described in Rosenberg and Krupin (see Figure 881 of the attached document) was a cruciform-shaped device with surface channels along its length draining aqueous from the anterior chamber directly into the suprachoroidal space. However, in a trial of this implant in 13 eyes with neovascular or end-stage glaucoma, four eyes developed hypotony, hyphema was a common complication and five eyes required surgical

revision of the device or a second implant (see paragraph bridging columns 1 and 2 on page 1784). To our knowledge, no shunt that relies on suprachoroidal drainage is in currently in regular clinical use.

In contrast, a shunt of the present invention overcomes the deficiencies in previous shunt designs. The “injectability” of a shunt according to the present invention minimizes trauma to the eye during insertion, such trauma being responsible for the majority of complications of previous designs. Specifically, as claimed in the present invention, the shunt is foldable to fit through a small incision across the anterior chamber and into the space under the sclera in the suprachoroidal space. The device incorporates a tube opening into and remaining in the anterior chamber. A shunt of the present invention will therefore result in greatly reduced fibrosis and enable longer term control of eye pressure than was not possible using shunts and procedures of the prior art.

Importantly, the production of scarring that accompanies the insertion of shunts, as discussed by Joseph at column 1, lines 42-52, and that particularly affects shunts that are on the surface of the sclera and under the conjunctiva is directly addressed by the shunt of the present invention, the basis for which is the fact that typically, there is little if any scarring that occurs in the suprachoroidal space, which is why cyclodialyses mostly do not heal spontaneously. Neither Joseph nor Molteno, when considered either separately or in combination, teach or suggest the placement of a shunt on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis.

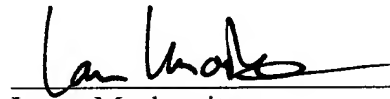
In view of the above, the Applicant submits that claims 1-9 are patentable over Joseph and Molteno, and therefore respectfully request reconsideration and withdrawal of the rejection.

Conclusion and Request for Interview

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. Additionally, Applicant respectfully requests a personal interview with the Examiner at her convenience. The Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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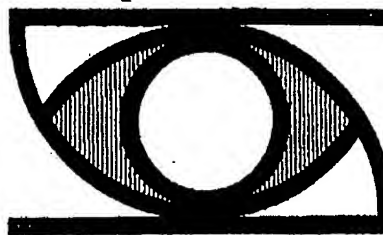
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Chapter 88



Implants in Glaucoma Surgery

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The limbal sclerostomy created during filtration surgery serves to bypass conventional outflow pathways and to permit aqueous humor to flow from the anterior chamber to the subconjunctival-Tenon's space. The surgical opening creates a low resistance pathway for aqueous flow and establishes an external filtration bleb. Adjunctive use of subconjunctival injections of 5-fluorouracil (5-FU)^{160,167} or intraoperative application of mitomycin C (MMC)^{20,146} or 5-FU¹⁴⁹ increases the chance of intraocular pressure reduction in eyes at high risk for filtration failure (see Chapter 81). However, satisfactory filtration may still be difficult to achieve in some cases. Plastic devices offer a different approach to intraocular pressure control. These implants have increased in popularity and are an alternative surgical treatment in eyes with poor surgical prognoses. Reduction of pressure by modern implants is accomplished by shunting of aqueous through an open tube from the anterior chamber to an area of encapsulation around an explant located 8 to 12 mm posterior to the limbus. The critical factor determining intraocular pressure reduction after implant surgery is the resistance of the capsular wall to aqueous humor flow and the total surface area of encapsulation.

HISTORICAL REVIEW

It became apparent early on that the classical glaucoma procedures of sclerectomy,⁴⁸ iridencleisis,⁵⁴ and corneoscleral trephination³⁵ were not uniformly successful in achieving long-term control of intraocular pressure. Foreign implantable materials were used to

maintain aqueous humor drainage through an ocular wound into the subconjunctival space. These early devices, which were true setons or stents to maintain patency of the fistula, may be categorized as paracentesis drains, cyclodialysis implants, or sclerostomy implants. Many of these devices were usually reported only once with limited experience and follow-up. In general, the long-term results were poor and the complications great, as a result of either excessive ocular inflammation or foreign body reaction leading to filtration failure.

Paracentesis Devices

Rollett and Moreau¹³¹ in 1906 reported placing a horse hair across the anterior chamber through paracentesis incisions to treat two patients with painful absolute glaucoma. Zorab¹⁷⁸ placed a double silk loop covered with a conjunctival flap through a superior keratome incision 2 mm behind the limbus, calling the procedure "aqueoplasty." Mayou,⁸⁷ Wood,¹⁷⁶ and Sampimon¹³⁴ reported good results with modifications of this procedure in patients with absolute glaucoma. A channelled silicone strip passed from the anterior chamber to the conjunctival sac was described in 1965 for treatment of neovascular glaucoma.⁸⁵ Vail¹⁶⁴ placed a silk thread in a track from the vitreous cavity into the subconjunctival space. The suture was removed at 3 months, and the glaucoma did not return for the 2 years before the patient's death. Nevertheless, long-term results with this group of devices were overall very poor because of infection, foreign body reaction, and inflammation.

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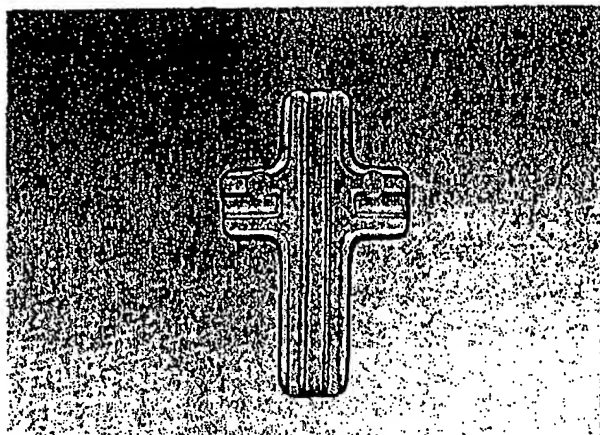


Fig. 88-1 The GlauRx trabeculo-suprachoroidal implant. Aqueous drains through surface channels within the cruciform-shaped implant. (Courtesy Alcon Surgical, Fort Worth, Tex.)

Cyclodialysis Implants

Many materials have been placed within a cyclodialysis with the aim of maintaining patency. In 1934 Row¹³² reported placing either a platinum wire or a horse hair within the cleft. Troncosco¹⁶² originally used a magnesium strip¹⁶³ and later tantalum foil. Others subsequently used inert plastics (Supramid, gelatin film, Teflon, silicone).^{*} Although these latter materials were well tolerated by the eye, long-term intraocular pressure lowering was poor, probably because of the overall unsuccessful results with cyclodialysis as a glaucoma surgical procedure.

The GlauRx implant (Alcon Surgical, Fort Worth, Tex) is a modern trabeculo-suprachoroidal shunt composed of a thin, cruciform-shaped device made of polymethyl methacrylate (Fig. 88-1). Surface channels along its length drain aqueous from the anterior chamber directly into the suprachoroidal space where it is absorbed.⁷³ Thus there is no resultant filtering bleb with this type of implant. Under a scleral flap, the long anterior end of the implant is inserted through an incision within the surgical limbus into the anterior chamber, and the posterior end of the implant is inserted through a parallel scleral incision overlying the suprachoroidal space. Thirteen eyes with neovascular or end-stage glaucoma were implanted with the GlauRx shunt.⁷² After a mean follow-up of 12 months (range, 7 to 24 months), 11 eyes had intraocular pressure less than 22 mmHg with or without antiglaucoma medication. Four eyes developed hypotony, with pressure less than 9 mmHg. Hyphema was a common

*References 3, 37, 68, 85, 121, 122, 132, 136, 152, 162.

complication. Five eyes (38%) required surgical revision of the device or a second implant.

Sclerostomy Setons

A silk thread was the first device to be placed translimbally from the anterior chamber to the conjunctival space.¹⁷⁸ This was followed by the variety of materials placed translimbally in attempts to prevent closure of the sclerostomy and to act as a "wick" promoting aqueous flow through the anterior chamber opening. These materials have included various plastic plates and rods, gold, tantalum, glass, platinum, cartilage, and lacrimal canalicular tissue.^{*} Most of these devices were associated with postoperative inflammation and fibrosis around the implant, which prevented aqueous humor egress.

Anterior Chamber Shunts to a Distant Site

Tube shunts have been used to direct aqueous from the anterior chamber to a distant site. Mascati¹²⁷ connected a plastic anterior chamber tube to the lacrimal sac, and Rajah-Sivayoham¹²⁷ connected a silicone anterior chamber tube to a superficial temporal vein. An anterior chamber-venous shunt using a catheter tube inserted into the intrascleral portion of the max vein was described by Lee and Wong⁷⁴ in 1974. Recently, an open plastic tube shunt from the anterior chamber to the angular vein has been reported.¹⁶⁹ Initial results with these shunts were good; however, there have been no long-term follow-up studies, and to our knowledge they are not frequently used. Obvious difficulties with these devices include erosion of the extraocular portion of the tube and reflux of contents (tears and blood) into the anterior chamber.

The short Krupin-Denver valve implant (see later discussion) has been used as an anterior chamber shunt to the conjunctival-tear surface.⁹ In addition, a modified valve implant containing a filter has been studied in monkey eyes, shunting aqueous humor to the tear layer.¹⁸ This concept provides resistance to aqueous humor flow by the slit-valve, thereby bypassing external (bleb) resistance. However, the potential for reverse flow (tears into the anterior chamber) and endophthalmitis is great, thereby limiting the clinical use of this concept.

Translimbal Tube Shunts

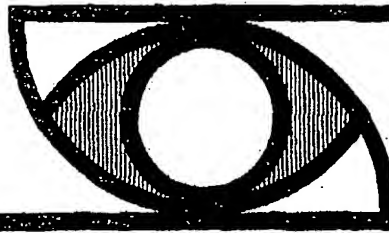
A plastic tube inserted at the limbus into the anterior chamber has the advantage of maintaining a patent conduit for aqueous flow to the subconjunctival space. The open end of the anterior chamber tube, and not the entry incision, is the effective "scleros-

*References 12, 13, 33, 37, 46, 70, 75, 85, 106, 126, 129, 155, 170.

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